

Atty. Docket No.:

4231/2055C

**PATENT** 

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of:

Choong-Chin Liew

Serial No.:

10/809,675

Filed:

March 25, 2004

Entitled:

Method for the Detection of

Osteoarthritis Related Gene

Transcripts in Blood

Examiner:

Switzer

Group Art Unit:

1634

Conf. No.:

8433

#### CERTIFICATE OF MAILING UNDER 37 C.F.R. § 1.8a

I hereby certify that this correspondence (and any paper or fee referred to as being enclosed) is being deposited with the United States Post Office as First Class Mail on the date indicated below in an envelope addressed to Mail Stop Amendment, Commissioner for Patents, P.O. Pox 1450, Alexandria, VA 22313-1450.

Kathleen Williams

Name of Person Mailing Paper

Signature of Person Mailing Paper

Mail Stop Amendment **Commissioner for Patents** P.O. Box 1450 Alexandria, VA 22313-1450

# TRANSMITTAL LETTER

Enclosed for filing in the above-identified patent application, please find the following documents:

- Information Disclosure Statement; 1.
- Form PTO-1449; and 2.
- Return Post Card. 3.

The Commissioner for Patents is hereby authorized to charge any fees to Deposit Account No. 16-0085, Reference 4231/2055C. A duplicate of this transmittal letter is enclosed for this purpose.

Date:  $\frac{10/18/05}{}$ 

Respectfully submitted,

Name: Name: Kathleen Williams

Registration No.: 34,380 Customer No.: 29933 Palmer & Dodge LLP

111 Huntington Avenue Boston, MA 02199-7613

Tel: 617-239-0100



Atty. Docket No.:

4231/2055C

**PATENT** 

#### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of:

Choong-Chin Liew

Serial No.:

10/809,675

Filed:

March 25, 2004

Entitled:

Method for the Detection of

Osteoarthritis Related Gene

Transcripts in Blood

Examiner:

Switzer

Group Art Unit:

1634

Conf. No.:

8433

## CERTIFICATE OF MAILING UNDER 37 C.F.R. § 1.8a

I hereby certify that this correspondence (and any paper or fee referred to as being enclosed) is being deposited with the United States Post Office as First Class Mail on the date indicated below in an envelope addressed to Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

Kathleen Williams

Name of Person Mailing Page

Signature of Rerson Mailing Pa

Mail Stop Amendment Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

# INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR §§§ 1.56, 1.97 AND 1.98

Dear Sir:

In accordance with the duty of disclosure under 37 CFR § 1.56, Applicant submits this Information Disclosure Statement pursuant to 37 CFR §§ 1.97 and 1.98 in the above-identified application for consideration by the Patent Office.

The attached Form PTO-1449 contains a listing of the cited documents. This application was filed after June 30, 2003, and copies of U.S. patents and U.S. patent applications are not required and are not enclosed. Accordingly, no copies are enclosed of documents numbered 1-28 on the attached Form PTO-1449.

No copies of foreign patent documents and non-patent literature which are listed on the attached Form PTO-1449 are enclosed as they have been previously submitted to the United States Patent and Trademark Office on an IDS or a supplemental IDS filed in the related U.S. patent applications of 10/268,730 and/or 10/601,518. Accordingly, no copies are enclosed of

Attorney Docket: 4231/2055C U.S. Serial No. 10/809,675

documents numbered 29-104 of the attached Form PTO-1449, since these documents were submitted previously with an IDS or a supplemental IDS filed ina related application. Specifically, no copies are enclosed of foreign patent documents numbered 29-35 and other documents numbered 48-70 and 72-87 since these documents were submitted previously with an IDS or a supplemental IDS filed in application serial number 10/268,730. Further, no copies are enclosed of foreign patent documents numbered 36-47 and other documents numbered 71 and 88-104, since these documents were submitted previously with an IDS or a supplemental IDS filed in application serial number 10/601,518.

Pursuant to CFR § 1.97(b)(3), because this Statement is being submitted before the first Office Action on the merits, no fee is required.

Applicant does not intend to represent that any of the documents submitted herein are material prior art to this invention or that the list represents an exhaustive search of documents related to this invention.

Applicant respectfully requests that the documents submitted herein be considered and made of record in this application.

Date: 10/18/05

Respectfully submitted,

Vame Name: Kathleen Wilhams

Registration No.: 34,380

Customer No.: 29933 Palmer & Dodge LLP 111 Huntington Avenue

Boston, MA 02199-7613

Tel: 617-239-0100

OLI SO SONS A

USPTO form 1449 U.S. Department of Commerce

Attorney Docket No. 4231/2055C

Serial No. 10/809,675

INFORMATION DISCLOSURE STATEMENT

Applicant(s): Choong-Chin Liew Filing Date: March 25, 2004

Group: 1634

Examiner		Patent No.	Date	Name	Class	Subclass	Filing Date
Initial	1	6,190,857	February 20,	Ralph et al.			
	2	6,218,529	2001 April 17,	An et al.	<del></del>		
	3	6,277,574	2001 August 21,	Walker, et a.			
.=			2001				
	4	5,853,996	December 29, 1998	Mordechai, et al.			
	5	6,251,590	June 26, 2001	Schweighoffer et al.			
	6	5,882,864	March 16, 1999	An et al.			
	7	5,942,385	August 24, 1999	Hirth			
-	8	6,479,263	November 12, 2002	Slawin et al.			•
	9	6,048,709	April 11, 2000	Falb et al.			
	10	6,124,433	September 26, 2000	Falb, et al.			
	11	6,486,299	November 26, 2002	Shimkets			
	12	6,525,185	February 25, 2003	Fan, et al.			
	13	5,352,775A	October 4, 1994	Albertson et al			
	14	5,837,449	November 17, 1998	Monia et al.			
	15	2003/0104393 A1	June 5, 2003	Sharp, Frank R. et al.	·		
	16	6,642,002	November 4, 2003	Loyd, et al.			
	17	6,630,301	October 7, 2003	Gocke, et al.		,	
-	18	6,692,916	February 17, 2004	Bevilacqua et al.		-	
	19	6,521,420	February 18, 2003	Herman, et al.		11=01	

	20	2003/0224374	Dec 200	cember 4,		ai, HongYı al.	ıe	<del>-</del>		<u> </u>		
	21 2002/0142981 Octo 2002		tober 3,		orne, Darci	i						
	22	2003/0180743	September 25, 2003		N	agasu et al.						, _
	23	2004/0121390	Jun			harma et al						
	24	5,739,432		ril 4, 1998	S	inha		-		-		
	25	6,607,898		gust 19,	K	opreski, et	al.					
	26	6,617,170	Sep 200	otember 9,	A	ugello, et a	1.					
	27	5,352,775	Oct 199	tober 4,	A al	lbertson et						
	28	5,837,449		vember, 1998	M	Ionia et al.						
FOREIGN	PATEN	T DOCUMENTS									· · · · ·	
Examiner Initial		Document No.		Publication Date		Country	С	lass	Sub	class		slation s No
	29	DE 44 35 919 C		07 DEC 199	5	GERMA NY						
	30	EP 0 534 640 A		31 MAR 1993		EPO						
	31	JP 09 187299		22 JUL 199	7	JAPAN						
	32	WO 98/18906		07 MAY 1998		PCT						
	33	WO 98/24935		11 JUN 199	8	PCT						
	34	WO 98/33942		06 AUG 1998		PCT						
	35	WO 98/49342		05 NOV 1998		PCT						
	36	WO/01/25473		04/12/2001		PCT						
	37	WO/03/040404		05/15/2003	,	PCT						
	38	WO/02/14547		Feb. 21, 2002		PCT						
	39	WO/03/061564		July 31, 2003		PCT				-		
	40	WO/03/086445		October 23 2003	,	PCT						
	41	WO/02/074986		September 26, 2002		PCT						
	42	WO/02/103320		December 27, 2002		PCT						
	43	WO/02/057414A	12	July 25, 2002		PCT					Front Page and	

							Abstra	
							ct	
				:			Only	
	44	WO/03/008647	01/30/2003	PCT			Omy	
	45	WO/03/090694	11/06/2003	PCT			!	
	46	WO/03/072827	09/04/2003	PCT				
	47	WO/04/061410	07/22/2004	PCT				
OTHER DO	CUME	ENTS (including Author		Pertinent Pa	iges, etc.)			
	48	Claudio, J.O. et al. (1						
	49	Chelly J et al. (1989)	. Proc. Nat. Ac	ad. Sci. US.	A. 86:261	7-2621		
	50	Chelly J et al. (1988)	. <i>Nature</i> 333:8	58-860.				
	51	Drews J & Ryser S (1	1997). <i>Nature 1</i>	Biotech. 15:	1318-9.			
	52	Ferrie RM et al. (199						
	53	Fu D-J et al. (1998).	Nat. Biotech 1	6: 381-4.				
	54	Gala JL et al. (1998).			. •			
	55	Geisterfer-Lowrance	AAT et al. (19	90). <i>Cell</i> 6	2:999-10	06.		
	56	Groden J et al. (1991	). Cell 66:589	-600.				
	57	Jandreski MA & Liev	w CC (1987). <i>F</i>	lum. Genet.	76:47-53	3.		
	58	Jin O et al. (1990). C	irculation 82:8	-16				
	59	Kimoto Y (1998). Ma	ol. Gen. Genet	258:233-23	9.			
	60	Koster M et al. (1996	6). Nat. Bioteci	h 14: 1123-	8			
	61	Liew & Jandreski (19	986). <i>Proc. Na</i> i	. Acad. Sci.	<i>USA</i> . 83:	3175-3179	)	
	62	Liew CC et al. (1990). Nucleic Acids Res. 18:3647-3651.						
	63	Liew CC (1993). J Mol. Cell. Cardiol. 25:891-894						
	64	Liew CC et al. (1994	). Proc. Natl. A	lcad. Sci. U	<i>SA</i> . 91:10	0645-10649	)	
	65	Liew et al. (1997). M	ol. and Cell. B	iochem. 172	2:81-87.			
	66	Niimura H et al. (199				57		
	67	Ogawa M (1993). Blo						
	68	Riccie et al. (1997) N			30-134			
	69	Santoro IM & Grode	n J (1997). <i>Car</i>	icer Res. 5	7:488-494	1.		
	70	Yuasa T et al. (1998)						***
	71	Marshall KW (1996)	Journal of Rhe	umatology	23(4):582	2-585		
1	72	Campbell, C.; Vernor				-	•	
		Assessment of Norma	•	ı Periphera	l Blood G	ene Expres	sion. Dise	ease
		Markers, 18:201-206			<u></u>			
	73	Yoshikai et al., "Genor <i>Gene</i> 87:257-263 (199	_	of the Hum	an Amylo	id Beta-Prec	cursor Gene	e′³
	74	GENBANK AC:V0050		Bell et al.: "	Sequence	of the Huma	an Insulin (	Gene"
		(XP002141055)	1 100	NO D	1 44 1	• .•	134 63	
	75	GENBANK AJ:00314' FMF Region" (XP002)		98, Bernot et	al., "A Tr	anscriptiona	I Map of th	ne
	76	GENBANK AC:M735		5, Joslyn et a	ıl., "Identii	fication of D	Deletion	
<del></del>		L	, , , , , , , , , , , , , , , , , , , ,		/			

		Mutations and Three New Genes at the Familial Polyposis Locus" (XP002141058)
	77	GENBANK AC:X52889, September 1993, Liew, "Complete Sequence and Organization
	77	of the Human Cardiac Beta-Myosin Heavy Chain Gene" (XP002141056)
<u> </u>	70	GENBANK AC:M54947, April 1993, Seidman et al., "Molecular Studies of the Atrial
	78	Natriuretic Factor Gene" (XP002141054)
	70	Nagai et al. "Decrease of the D3 dopamine receptor mRNA expression in lymphocytes
	79	
	00	from patients with Parkinson's disease," <i>Neurology</i> 46:791-795 (1996)  Mattano et al. "Sensitive Detection of rRare Circulating Neuroblastoma Cells by the
	80	
	01	Reverse Transcriptase-Polymerase Chain Reaction Cancer Research 52:4701-4705 (1992)  Katz et al. "Molecular Staging of Prostate Cancer with the Use of an Enhanced Reverse
	81	
	- 02	Transcriptase-PCR Assay" <i>Urology</i> 43(6):765-775 (1994)  Burchill et al. "Neuroblastoma cell detection by reverse transcriptase-polymerase chain
	82	
	- 02	reaction (RT-PCR) for tyrosine hydroxylase mRNA" Int. J. Cancer 57:671-675 (1994)
	83	Johnson PWM et al. "The molecular detection of circulating tumor cells", British Journal
	0.4	of Cancer 72:268-275 (1995), PAGES 268-276 Seiden et al. Detection of Curculating Tumor Cells in Men with Localized Prostate Cancer
	84	Journal of Clinical Oncology 12(12):2634-2639 (1994)
-	0.5	Moreno J.G. et al. "Detection of Hematogenous Micrometastasis in Patients with Prostate
	85	Cancer" Cancer Research 52:6110-6112 (1992)
	96	Hannon et al. NCCLS "Blood Collection on Filter Paper for Newborn Screening
	86	Programs; Approved Standard—Fourth Edition—NCCLS document LA4-A4 [ISBN 1-
		56238-503-8] NCCLS, 940 West Valley Road, Suite 1400, Wayne Pennsylvania 19087
		USA (2003) Vol. 23 No.21. Pages 1-31
	87	Ernst et al. NCCLS "Procedures and Devices for the Collection of Diagnostic Capillary
	07	Blood Specimens; Approved Standard—Fifth Edition. NCCLS document H4-A5 [ISBN 1-
		56238-538-0]
]		NCCLS, 940 West Valley Road, Suite 1400, Wayne Pennsylvania 19087 USA (2004) Vol.
		24 No.21. Pages 1-47
	88	Kopreski Michael, S. et al. August 1999, "Detection of Tumor Messenger RNA in
	00	the Serum of Patients with Malignant Melanoma", Clinical Cancer Research Vol
		5: 1961-1965
	90	
	89	Vernon, S.D. et al; (2002) "Utility of the Blood for Gene Expression and Profiling
		and Biomarker Discovery in Chronic Fatigue Syndrome, Disease Markers, 18: 193-
		199
	90	Dasi, Francisco et al. (May 2001) Real-Time quantification in plasma of human
		telomerase reverse transcriptase (hTERT) mRNA: A simple blood test to monitor
		disease in cancer patients. Laboratory Investigation, Vol. 81, No. 5, p.767-769,
	91	Fleischhacker, Michael et al. (Sept 2001) Detection of Amplifiable Messenger RNA
		in the Serum of Patients with Lung Cancer Annals. NY Acad Sciences 945:179-
]		188
	92	Gal, Shira et al. (Sept 2001) Detection of Mammaglobin mRNA in the Plasma of
		Breast Cancer Patients Annals, N Y Acad Sciences, 945:192-194
	93	Zhang, H.Q., Lu, H., Enosawa, S. Takahara, K. Sakamoto, T. Nakjima, H. S. and
	73	
		Suzuki, S. (2002) Microarray analysis of Gene Expression in Peripheral Blood
]		Mononuclear Cells Derived from Long-Surviving Renal Recipients, Transplantation
	_	Proceedings 34 1757-1759
	94	
		Espe, K.J., Shark, K.B., Grande W. J. Hughes, K.M., Kapur, V., Gregersen, P.K.
	94	Baechler, E.C., Batliwalla, F. M., Karypis, G. Gaffney, P.M.; Ortmann, W.A. Espe, K.J., Shark, K.B., Grande W. J. Hughes, K.M., Kapur, V., Gregersen, P.K.

		and Behrens, T.W. (March 4, 2003) Interferon-inducible gene expression signature
		in Peripheral Blood Cells of Patients with Severe Lupus. PNAS 100 (5):2610-5.
9	)5	Lo, Y.M. Dennis (2001 Sept.) Circulating Nucleic Acids in Plasma and Serum:
		An Overview, Ann N Y Acad Scien 945: 1-7
9	95	Ng, Enders K.O., Tsui, N.B.Y., Lam, NYL, Chiu, R.W.K., Yu, S.C.H., Wong,
		S.C.C., Lo, E.S.F., Rainer, T.H., Johnson, P.J., and Lo, Y.M.D. (August, 2002)
		Presence of Filterable and Nonfilterable mRNA in the Plasma of Cancer Patients
		and Healthy Individuals. Clin. Chem. 48(8):1212-1217
9	6	Mengelle, C. Sandres-Saune, K. Pasquier, C. Rostaing, L. Mansuy, J-M, Marty, M.
		Da Silva, I., Attal, M., Massip, P. and Izopet, J. (Aug 2003) Automated Extraction
		and Quantification of Human Cytomegalovirus DNA in Whole Blood by Real-Time
		PCR Assay. J. Clin. Microbiology, 41(8):3840-3845
9	97	Samuel DePrimo et al. (2003) Expression profiling of Blood Samples from an
1		SU5416 Phase II Metastatic Colorectal Cancer Clinical Trial: A novel strategy for
		biomarker identification. BMC Cancer, 3(3): 1-12
9	8	Taback B. et al. (Dec 15, 2001) Detection of Occult Metastatic Breast Cancer Cells
		in Blood by a Multimolecular Marker Assay: Correlation with Clinical Stage of
		Disease. Cancer Research, 61:8845-8850
9	9	Schuster R. et al. (2003) Quantitative Real-Time RT-PCR for Detection of
		Disseminated Tumor Cells in Periphral Blood of Patients with Colorectal Cancer
		Using Different mRNA Markers. Int. J. Cancer. 108:219-227
10	00	Twine et al. (September 15, 2003) Disease Associated Expression Profiles in
		Peripheral Blood Mononuclear Cells from Patients with Advanced Renal Cell
		Carcinoma. Cancer Research, 63:6069-6075
10	01	Vawter M. et al. (2004) Microarray screening of lymphocyte gene expression
		differences in a multiplex schizophrenia pedigree, Schizophrenia Research, 67
		(2004):41-52
10	02	
		Neumann et al. (Jan 2002) Identification of differentially expressed genes in
		rheumatoid arthritis by a combination of complementary DNA array and RNA
		arbitrarily primed-polymerase chain reaction. Arthritis Rheum. 46(1):52-63.
10	03	Schwering, I. et al. (2003) Profiling of Hodgkin's lymphoma cell line L1236 and
		germinal center B cells: identification of Hodgkin's lymphoma-specific genes,
		Molecular Medicine, No. 3-4: 85-95
10	04	Martin, K. et al (2001) High-sensitivity array analysis of gene expression for the
		early detection of disseminated breast tumor cells in peripheral blood Proceedings
		of National Academy of Sciences, Vol. 98, No. 5: 2646-2651
EXAMINER		DATE CONSIDERED

\*EXAMINER: Initial reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

\*\* Copies of references not provided at the time of this submission.